

Initiative 23-0013 Amdt. 1

August 23, 2023

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Office of the Attorney General  
1300 "I" Street, 17th Floor  
Sacramento, CA 95814

Aug 23 2023

INITIATIVE COORDINATOR  
ATTORNEY GENERAL'S OFFICE

Attention: Initiative Coordinator

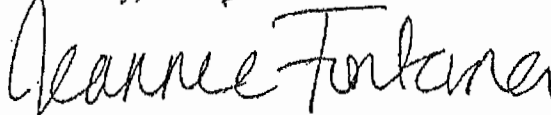
Re: *Submission of Amendments to TREAT California Act 23-0013, and  
Request to Prepare Circulating Title and Summary (Amendment)*

Dear Initiative Coordinator:

On July 19, 2023, I submitted a proposed statewide initiative titled "*TREAT California Act*," ("Initiative") and submitted a request that the Attorney General prepare a circulating title and summary pursuant to section 10(d) of Article II of the California Constitution.

Pursuant to Elections Code section 9002(b), I hereby submit timely amendments to the text of the Initiative. I have also enclosed a redline version showing the differences from the original Initiative. As the proponent of the Initiative, I approve the submission of the amended text to the Initiative and I declare that the amendment is reasonably germane to the theme, purpose, and subject of the Initiative. I respectfully request that the Attorney General prepare a circulating title and summary using the amended Initiative (Amendment).

Sincerely,



Jeannie Fontana

Enclosures

This initiative measure is submitted to the people in accordance with the provisions of Section 8 of Article II of the California Constitution.

This initiative measure expressly amends the California Constitution by adding an article thereto; and amends a section of the Government Code and adds sections to the Health and Safety Code; therefore, new provisions proposed to be added are printed in italic type to indicate that they are new.

## PROPOSED LAW

### SECTION 1. Title.

This measure shall be known as the “TREAT California Act.”

### SECTION 2. Findings and Declarations.

(a) The people of California find and declare the following:

(1) We stand on the brink of a transformative moment in the field of mental healthcare, with the power and potential to address some of society’s most daunting challenges, including homelessness, addiction, PTSD, suicide, and beyond.

(2) At the center of this moment is the **TREAT California Act**, a citizen-driven ballot initiative representing a profound shift in our approach to mental health treatment; this initiative focuses on plant-derived compounds, known as “psychedelic medicines,” which have shown immense promise in treating mental health.

(3) The introduction of psychedelic-assisted therapy (PAT), a fusion of traditional talk therapy with 1-3 medicinal sessions, provides therapists with an unparalleled **new tool**. The outcomes of clinical trials are nothing short of revolutionary, demonstrating the effectiveness and potential of this approach. PAT focuses on addressing the root cause of mental health issues rather than merely treating the symptoms, providing a more comprehensive and effective treatment.

(4) To date, the trials have been funded through philanthropy on a small scale. We need to fund research and large-scale clinical trials on these promising therapies to bring them to those in need. The TREAT California Act focuses on **treatments, research, education, access, and therapies** for mental health, including addiction, pain, end of life anxiety and more. The goal is to improve the lives of millions, and ensure cost effective therapies that are accessible to all.

(5) The passage of the TREAT California Act on November 5, 2024, will create a \$5 billion state funding agency tasked with bringing these medicines to the public in a safe, responsible, and ethical manner. The agency is funded by California general obligation bonds, with interest spread over decades.

(6) Homelessness has reached alarming proportions, with more than 75% of the homeless struggling with mental health. The overdose crisis adds to the gravity of the situation,

contributing to nearly 300 Americans dying every day from opioid-related overdose. In August 2023, the Drug Enforcement Administration declared fentanyl the number one cause of death for Americans under 50 years old.

(7) Suicide rates, particularly among veterans and first responders, further underline the urgency. California is home to nearly 2 million veterans, with many of them suffering from PTSD, substance use disorder, anxiety, and depression. An average of 40 veterans die every day in the US from suicide or self-injury, and suicide has become the second leading cause of death among firefighters.

(8) The young adults and children are not spared from this crisis. The Centers of Disease Control reported that 44% of adolescents felt “persistently sad or hopeless,” nearly 20% had seriously contemplated suicide, and 9% had attempted suicide. Suicidal thoughts in children as young as five years old increased nearly 60% (since COVID-19).

(9) The lack of effective treatments has enormous costs to Californians. The true economic cost of mental healthcare is a complex figure to pinpoint but we all pay for this, through our suffering and through our taxes. The cost of substance use disorder alone in California was estimated at \$172.6 billion in 2010. The opioid epidemic is just one of many mental health issues facing the country. According to the most recent data from the CDC (2017), the cost of this specific crisis was estimated at \$1,021 billion in the U.S., with California’s cost being \$61 billion.

(10) Even a modest 10% success rate in treating opioid use disorder in California could save nearly \$6 billion annually, more than the bond proceeds that would fund the TREAT Institute.

(11) The TREAT California Act will not legalize or decriminalize these medicines. It will provide funding to run clinical trials to determine safety, efficacy, and appropriate indications for mental health issues. Once approved by the FDA, these medicines will be administered by a licensed care providers in a supervised setting.

(12) The TREAT California Act will establish the state as the national leader in mental health treatment, setting a new standard for care and compassion.

### SECTION 3. Purpose and Intent.

It is the intent of the people of California in enacting this measure to:

(a) Establish a new state institute known as the TREAT Institute (“TREAT”) to award grants and loans for psychedelic research and to expand the ecosystem necessary to promote access to therapies for all Californians regardless of ability to pay.

(b) Authorize an average of \$500 million per year over a 10-year period to provide funding for research into the therapeutic potential of psychedelic medicines, with the goal of improving mental health outcomes and treatment options for Californians through cost-effective therapies reducing the fiscal burden on our taxpayers and government.

(c) Fund treatments, research, education, access, and therapies for mental health, addiction, pain, and wellbeing using psychedelic therapies at universities and other medical research facilities that have a track record of successfully conducting research and clinical trials.

(d) Maximize the use of research funds by giving priority to research that has the greatest potential for therapies and cures, specifically building upon existing promising research results. Priority will also be given to research in areas of great need such as substance use disorders, addictions, anxiety, depression, suicidality, and PTSD. TREAT will also fund the infrastructure and expertise necessary to deliver therapies to patients, including, but not limited to, product development, manufacturing, clinical validation, regulatory approvals, care provider education, certification, oversight, and risk stratification.

(e) Ensure that the research is conducted safely, ethically, and culturally appropriately by requiring compliance with standards based on national models that protect patient safety, rights, and privacy; and by including consultation with religious, Native American, and Indigenous leaders.

(f) When, and if, the FDA approves MDMA for the treatment of PTSD and psilocybin for major depressive disorder, TREAT shall support access to care programs in California.

(g) Ensure that the funding is spent responsibly by funding milestone-based research and terminating funding if awardees do not meet their milestones, or if the research is deemed to be unsafe or ineffective.

(h) Improve the California healthcare system and reduce the long-term healthcare cost burden on California by identifying effective therapies for mental health issues, modeling and measuring the economic impact of new effective therapies in making health care more cost effective, and promoting access to, and the affordability of, mental health treatments for all Californians, regardless of economic means.

(i) Require strict fiscal and public accountability through mandatory independent audits, open meetings, public hearings, and annual reports to the public, and through the creation of an independent oversight board selected by California's elected leaders charged with bringing these new therapies to the public in a safe, cost-effective way, and making them accessible to all.

(j) Create working groups that report to the board and are composed of experts in their fields, advocates, and stakeholders and ensure that these working groups include individuals with diverse backgrounds and experience.

(k) Protect and benefit the California budget: by postponing general fund payments on the bonds for the first five years; by funding scientific and medical research that will significantly reduce state healthcare costs in the future; and by providing an opportunity for the state to benefit from shared revenue, patents, and licensing fees that result from the research.

(l) Benefit the California economy by creating projects, jobs, and potentially therapies that will generate millions of dollars in new tax revenues in our state.

(m) Advance the biotech industry in California to world leadership, as an economic engine for California's future.

SECTION 4. Article XXXVI is added to the California Constitution, to read:

*Article XXXVI. Treatments Research Education Access & Therapies Institute*

*SEC. 1. There is hereby established the Treatments Research Education Access & Therapies Institute, hereinafter, TREAT.*

*SEC. 2. TREAT shall have the following purposes:*

*(a) To provide direct funding, grants, and loans:*

*(1) For clinical trials to evaluate the safety and effectiveness of psychedelic medicines for the treatment of mental health conditions and health disorders that may be helped by these medicines, including, but not limited to, post-traumatic stress disorder, anxiety, depression, addiction, suicidality, pain, inflammatory disorders, Alzheimer's disease, traumatic brain injury, and other diseases and conditions, and to promote wellbeing;*

*(2) For basic scientific research to understand the mechanisms of action of psychedelic medicines and their potential therapeutic benefits;*

*(3) For training and education programs for researchers, care providers, students, first responders, peer counselors, and the general public on the use of psychedelic medicines and psychedelic therapies in treatment;*

*(4) To support delivery of therapeutics to the people of California, including promoting access and affordability, and developing reimbursement models;*

*(5) To expand the infrastructure and expertise necessary to discover, develop, and deliver psychedelic therapies to patients, including, but not limited to, product development, manufacturing, clinical validation, regulatory approvals, care provider training, certification, oversight, and risk stratification.*

*(b) To support all stages of the process of developing treatments, from laboratory research through translational activities and successful clinical trials, to delivering psychedelic therapies to the public.*

*(c) To establish the appropriate regulatory standards and oversight for research and psychedelic therapy delivery.*

*(d) To provide transparency to the citizens of California.*

*SEC. 3. TREAT shall not support the harvesting or use of peyote (*Lophophora williamsii*) in order to avoid adverse environmental or cultural effects and negative effects on the future of*

*these sources, provided that, TREAT may support the use of synthetic versions of this psychedelic medicine, or versions of this psychedelic medicine that are derived from sources that do not pose adverse environmental or cultural effects.*

*SEC 4. TREAT shall consult with religious, Native American, and Indigenous leaders to ensure culturally respectful and ethical practices. Over-commercialization, exploitation, or misappropriation of psychedelic medicines may cause harm to Native American and Indigenous people's religions, communities, and cultures. As such, TREAT shall balance the potential of psychedelic medicines with the importance of cultural sensitivity and ethical stewardship.*

*SEC. 5. Funds authorized for, or made available to, TREAT shall be continuously appropriated without regard to fiscal year, be available and used only for the purposes provided in this article, and shall not be subject to appropriation or transfer by the Legislature or the Governor for any other purpose.*

*SEC. 6. There is hereby established a right to conduct research in California using all psychedelic medicines, natural and synthetic, except as provided in Section 3.*

*SEC. 7. Notwithstanding any other provision of this Constitution or any law, TREAT, which is established in state government, may utilize state issued tax-exempt and taxable bonds to fund its operations, medical and scientific research, capital expenditures, facilities, and other programs.*

*SEC. 8. Notwithstanding any other provision of this Constitution, including Article VII, or any law, TREAT and its employees are exempt from civil service.*

*SEC. 9. TREAT shall be governed by the TREAT Oversight Board. The members of the Board shall be considered state officers for purposes of Section 8 of Article III. The annual salary and the medical, dental, insurance, and other similar benefits received by the Board members shall be determined by the California Citizens Compensation Commission, based on the amount of the annual salary and the medical, dental, insurance, and other similar benefits received by executives employed by the University of California system.*

*SEC. 10. Notwithstanding Sections 6 and 17 of Article XVI of this Constitution, TREAT is authorized to acquire and hold shares of capital stock; and the holding of the stock shall entitle TREAT to all of the rights, powers and privileges, and shall subject TREAT to the obligations and liabilities conferred or imposed by law upon other holders of stock in the company or corporation in which the stock is so held.*

SECTION 5. Division 121, Part 1, Chapter 1 (commencing with Section 152000) is added to the Health and Safety Code, to read:

**Division 121. TREAT California**  
**Part 1. TREAT California**  
**Chapter 1. TREAT California Act**

**152000. TREAT Oversight Board.**

*This chapter implements Article XXXVI of the California Constitution, which established the Treatments Research Education Access & Therapies Institute (TREAT or the Institute).*

**152001. Goals of the TREAT Institute.**

*The Institute shall have the following goals:*

- (a) Improving mental health outcomes and treatment options for patients.*
- (b) Developing and delivering psychedelic therapies to Californians in a cost-effective manner.*
- (c) Promoting access to psychedelic therapies by all Californians.*

**152002. Programs of the Institute.**

*The Institute shall meet its goals through the programs described in sections 152003 through 152009:*

**152003. Clinical Trials and Research.**

*TREAT shall be committed to understanding and applying psychedelic therapies to treat mental health conditions and health disorders. TREAT shall be responsible for executing rigorous research protocols, forging vital collaborations between researchers and practitioners, designing and funding clinical trials and basic research, exploring and potentially developing and operating a brain imaging coalition, ensuring safety and risk reduction, and implementing long-term follow-up programs. TREAT shall prioritize funding for clinical trials that have the greatest potential for therapies and cures, including trials that build upon existing promising research results, and trials that address substance use disorders, anxiety, depression, suicidality, and PTSD.*

*(a) Clinical Trials*

*TREAT shall sponsor clinical trials at established research institutions or contract organizations to assess the safety, efficacy, and development of psychedelic therapies for mental health conditions and other health disorders. These evaluations will also compare psychedelic therapies to alternative treatments.*

*(1) The clinical trials supported by TREAT shall include:*

*(A) Clinical trials studying the use of psychedelic-assisted therapy to treat:*

*(i) addiction to alcohol, nicotine, opioids and other illicit drugs, gambling, pornography, social media, and other addictions;*

*(ii) anxiety and depression;*

*(iii) suicidality, including the use of psychedelic therapies as an intermediate intervention for suicidality;*

*(iv) PTSD, including evaluating the best psychedelic therapies to treat different populations struggling with PTSD, including:*

*(I) Research to evaluate the efficacy and effectiveness of programs to target the needs of veterans who struggle with PTSD;*

*(II) Research to evaluate the efficacy and effectiveness of programs to target the needs of firefighters and other first responders who struggle with PTSD;*

*(III) Research to evaluate the efficacy and effectiveness of utilizing female care providers to provide specialized programs to women who struggle with PTSD from sexual trauma or abuse, including programs that draw on learnings from “Athena” programs*

*(IV) Research to evaluate the efficacy and effectiveness of programs to target the needs of men who struggle with PTSD from sexual trauma or abuse, including men who become abusers after having been victims, including programs that draw on learnings from “Aqualung” programs;*

*(V) Research to evaluate the efficacy and effectiveness of specialized programs to target the needs of those who struggle with PTSD from childhood sexual trauma or abuse;*

*(VI) Research to evaluate the efficacy and effectiveness of programs to target the needs of members of the LGBTQIA+ community who struggle with mental health, including programs that draw on learnings from “Born This Way” programs;*

*(VII) Research to evaluate the efficacy and effectiveness of treatment options for those who struggle with PTSD from causes other than the above, such as physical abuse, childhood neglect, accidents, race-based trauma, trauma related to drug criminalization or contact with the criminal legal system, and other traumas;*

*(v) chronic and acute pain, including, but not limited to, pain caused by cancer, phantom limb, headaches, fibromyalgia, and musculoskeletal disorders;*

*(vi) other health conditions and health disorders, such as, but not limited to, traumatic brain injury, stroke, fear of death and dying, Alzheimer’s disease, obsessive-compulsive disorder, anorexia nervosa, attention-deficit disorder, and asthma.*

*(B) Clinical trials studying the safety and efficacy of microdosing psychedelic medicines.*



*(C) Clinical trials studying the safety and efficacy of psychedelic therapies when administered concurrently with antidepressants or other psychiatric medications.*

*(D) Clinical trials studying the safety and efficacy of psychedelic therapies when administered in connection with concomitant therapies.*

*(E) Clinical trials studying the optimal treatment regimens for different mental health conditions and health disorders including, but not limited to, the most effective and efficient ratio of practitioners to patients and the optimal number of sessions.*

*(F) Clinical trials studying the safety and efficacy of psychedelic therapies in adolescents and young adults and the ideal age of intervention for these populations.*

*(G) Long-term clinical trials to study the long-term impact of psychedelic therapy programs on patients.*

*(H) Clinical trials studying the effect of psychedelic therapies on wellbeing, including, but not limited to, religious and spiritual wellbeing.*

*(2) TREAT shall identify, develop, and adopt designs and algorithms for clinical trials in order to best achieve the goals of accelerating enrollment, ensuring efficiency and compliance, ensuring the safety of research participants, and generating the highest quality data. Without limiting the foregoing:*

*(A) TREAT shall design clinical trials to rectify existing diversity gaps, collaborating with specialists, community leaders, and other stakeholders. TREAT shall seek to ensure inclusive representation, encompassing groups such as people of color, women, and the LGBTQIA+ community.*

*(B) TREAT shall seek to promote the participation in clinical trials of members of populations most in need of treatment, such as veterans and first responders, by prioritizing trials that support the enrollments of individuals from these populations.*

*(C) TREAT shall seek to identify the most cost-effective way to implement trials, including, but not limited to, by:*

*(i) conducting all trials in California; provided, however, that if trials are limited because of a lack of patients, TREAT may support the use of trial sites outside of California; and*

*(ii) considering the use of contract research organizations along with, or in place of, academic institutions for trial operations.*

*(D) TREAT shall establish a Data and Safety Monitoring Board (DSMB) modeled on National Institutes of Health guidelines to evaluate the safety of trials and to evaluate and address any adverse events.*

*(E) TREAT shall establish standards, in addition to the standards required by Sections 152008 and 152030, to ensure the safety of research participants including, but not limited to standards addressing:*

*(i) training to ensure that research participants are safe from harm caused by violations of the research participants' treatment boundaries;*

*(ii) the needs of those research participants who, at the end of a trial, are still vulnerable; and*

*(iii) screening of research participants.*

*(b) Basic Research*

*TREAT shall operate as a traditional peer-reviewed grantmaking agency, issuing requests for proposals, utilizing the Clinical Trial and Research Working Group to evaluate applications submitted in response to these proposals, with an emphasis on collaboration and innovative problem-solving. TREAT may fund basic research in areas including, but not limited to, the following:*

*(1) The use of psychedelic medicines to stimulate neuronal growth in order to slow the progression of neurological disorders such as, but not limited to, Alzheimer's disease, Parkinson's Disease, ALS, headaches, traumatic brain injury, allergies, asthma, autism, and other mental health conditions and health disorders.*

*(2) The role of the microbiome in mental health.*

*(3) The efficacy of genomic sequencing of research participants. To further this research, TREAT shall develop a large-scale, open-access genomic data bank that matches genetic markers with phenotypic expression, as well as the age, sex, race, and mental health disorder of research participants.*

*(4) The identification and tracking of biomarkers for mental health disorders.*

*(5) The identification and study of derivatives of psychedelic medicines to identify new medicines.*

*(c) Brain Imaging Coalition*

*TREAT shall explore the creation of a Brain Imaging Coalition to help improve the resolution of brain imaging technologies in support of the study of psychedelic therapies, and if it determines such a coalition would be feasible and effective, may establish such a coalition.*

*(d) Wellbeing*

*TREAT shall develop criteria to define, measure, and track wellbeing in order to evaluate the effectiveness of psychedelic therapies and provide long-term tracking of wellbeing outcomes.*

*(e) Risk Stratification*

*TREAT shall develop criteria to define, measure, and track risk stratification in order to evaluate the effectiveness of psychedelic therapies, provide long-term tracking of outcomes, and identify contraindications for psychedelic therapies.*

*(f) Long-Term Monitoring*

*TREAT shall develop criteria for tracking long-term patient outcomes that include, but are not limited to, the following:*

- (1) Determining if successful treatment of one addiction impacts other addictive behaviors.*
- (2) Determining the best method to collect evidence of safety and effectiveness outside of clinical trials.*
- (3) Determining the best method to collect data associated with decriminalization or legalization.*
- (4) Collecting data related to the effect of psychedelic therapies on those who are incarcerated, those who are homeless, domestic violence reports and arrests, and rates of recidivism.*

**152004. Education.**

*TREAT shall support the training of care providers to administer psychedelic-assisted therapy and other psychedelic therapies, and shall educate the public about psychedelic therapies. TREAT shall support the training of its staff, researchers, and care providers regarding religious and cultural issues, and ethical obligations with respect to the medicines, knowledge, and practices of Native Americans and Indigenous peoples.*

*(a) Care Provider Training*

- (1) TREAT shall collaborate with existing licensing agencies to create a supplemental certification program to certify licensed practitioners (including, but not limited to, Medical Doctors, Doctors of Osteopathic Medicine, Doctors of Philosophy, Doctors of Psychology, Licensed Marriage and Family Therapists, Licensed Clinical Social Workers, Licensed Professional Clinical Counselors, Physician Assistants, and Registered Nurses) as well as first responders and peer counselors, who can participate in clinical trials and if TREAT is unable to establish such a program within an existing licensing agency, TREAT shall be authorized to establish its own certification program.*
- (2) TREAT shall seek to expand the certification of psychedelic-assisted therapy-credentialed care providers to utilize the wealth of knowledge of practitioners who are not licensed, such as, but not limited to, religious, spiritual, and traditional practitioners, in order to promote the incorporation of their practices into FDA-approved clinical trials.*

*(3) TREAT shall develop a program to increase the number of qualified psychedelic-assisted therapy care providers, through the following efforts:*

*(A) Defining and outlining certification for specialized care providers that includes curricula and best practices for training, certification, regulation, and oversight.*

*(B) Seeking to provide accredited therapy training programs in California's university system.*

*(4) TREAT shall develop a program to train and supervise care providers to provide safe and effective care for all patients, which will include bias and cultural and religious competency training.*

*(A) Public Education*

*TREAT shall develop a statewide education program to educate the public about mental health, the potential, risk, and appropriate uses of psychedelic medicines, as well as the activities of the Institute, with the following goals:*

*(1) Fostering trust through transparency about TREAT's operations.*

*(2) Ensuring the information disseminated is current, accurate, and backed by credible sources.*

*(3) Ensuring that education programs are inclusive, accessible, and understandable to a broad range of demographics.*

*(4) Utilizing a range of communication channels to enhance reach and impact.*

*(5) Supporting mental health education in school curricula at every level.*

*(6) Engaging in targeted outreach and educational initiatives within communities, including working closely with community leaders, non-profit organizations, and local health care providers to build trust, awareness, and understanding about the benefits of psychedelic therapies and how to access them.*

**152005. Access.**

*TREAT shall seek to ensure that all California residents have access to psychedelic therapies, regardless of their financial means, and to eliminate barriers to accessing care.*

*(a) TREAT shall seek to expand access to care by:*

*(1) Exploring the feasibility of, and implementing if feasible, financial assistance programs to promote the affordability of psychedelic therapies for all Californians, and particularly for those in underserved communities, regardless of income level.*

- (2) Building relationships with insurance companies to facilitate the inclusion of psychedelic therapies in insurance plans.*
  - (3) Establishing partnerships with healthcare providers, hospitals, and clinics across California to make psychedelic therapies available to all communities, focusing on underserved populations.*
  - (4) Conducting community outreach and education programs to inform Californians about the availability of psychedelic therapies and how to access them.*
  - (5) Engaging in advocacy efforts to influence policy decisions that impact access to psychedelic-assisted therapy.*
  - (6) Exploring the feasibility of establishing, and implementing if feasible, psychedelic therapies in locations that are easily accessible.*
  - (7) Monitoring and evaluating the effectiveness and impact of these programs on an ongoing basis.*
- (b) TREAT shall study the feasibility of, and implement if feasible, policies to improve reimbursement and market access for psychedelic therapies throughout California.*
  - (c) TREAT shall support the use of existing facilities, including academic institutions and private clinical practices, for patients to participate in clinical trials studying psychedelic therapies. TREAT shall evaluate the feasibility of, and implement if feasible, expanding facilities throughout California, particularly in rural communities and inner cities.*
  - (d) TREAT shall integrate its programs and initiatives with existing healthcare services and resources to ensure that TREAT programs complement and enhance existing services rather than duplicate them.*
  - (e) TREAT shall develop a robust and efficient distribution strategy to ensure that psychedelic therapies are readily available to those who need them. This may involve partnerships with healthcare providers, community organizations, and logistics companies. The strategy shall prioritize reaching underserved communities and populations, and aim to overcome barriers related to geography, income, and stigma.*

#### **152006. Technology.**

*TREAT shall use innovative technology, including, but not limited to, artificial intelligence and machine learning, to propel its mission, including by exploring the feasibility of, and if feasible, the implementation of the following:*

- (a) A comprehensive, Centralized Mental Health and Wellbeing Biobank to track and analyze data obtained through clinical trials. If the Board determines that the Biobank is feasible and would advance the objectives of the Institute, the Board may authorize the creation of the Biobank.*

*(1) Subject to paragraph 2 of this subdivision, TREAT shall make data in the Biobank available to researchers and clinicians throughout the world.*

*(2) TREAT shall enact standards to (i) ensure that data in the Biobank is stored and used with the consent of research participants; (ii) ensure the protection of research participant confidential information; and (iii) ensure that recipients of the data share revenues generated from the use of the data pursuant to Section 152028.*

*(3) If the Biobank is established, TREAT shall explore the feasibility of, and if feasible, implement, tracking changes in measurable consequences of substance use disorders such as DUIs, incarceration/recidivism, homelessness, and domestic violence.*

*(b) Developing software applications for tracking data from clinical trials and other sources.*

### **152007. Industry.**

*TREAT shall foster alliances and engage with industry and other relevant stakeholders regarding drug development, manufacturing, and commercialization efforts, therapy delivery, and other efforts to advance the efficacy of psychedelic therapies, including through technology, to ensure the safe and cost-effective delivery of psychedelic therapies.*

#### *(a) Public-Private Partnership Platform*

*TREAT shall establish a public-private partnership platform that will aim to work with for-profit entities in the technology, biotech, drug discovery, and related sectors to help deliver psychedelic therapies responsibly, ethically, and safely with an objective of creating a financially sustainable model to fund TREAT's programs while benefiting the General Fund. The public-private partnership platform will contain the following components:*

*(1) A multi-disciplinary selection committee will accept proposals from interested companies and will assess those proposals based on their alignment with TREAT's mission, financial viability, technical capabilities, ethical considerations, and potential for societal impact—including the impact on religious, Native American, Indigenous, or other cultural practices.*

*(2) Selected companies will be given access to TREAT's infrastructure for product validation and verification and training and capacity-building support. TREAT shall ensure that all products meet the required standards for safety, efficacy, and quality.*

*(3) Selected companies will provide TREAT with a licensing fee and a commission on revenues as provided by Section 152028. In lieu of, or in addition to, monetary payments, TREAT may accept compensation in the form of equity in the selected company.*

*(4) TREAT shall regularly monitor and evaluate partnerships to ensure the delivery of expected benefits and alignment with TREAT's objectives. TREAT may adjust or terminate partnerships if a selected company fails to meet the established performance criteria.*

*(5) All partnerships shall be memorialized in a written agreement that will be made available to the public, subject to the exclusions in subdivision (b) of Section 152025. The terms of each agreement shall require that the selected company complies with all relevant laws and all guidelines established by TREAT.*

*(b) Drug Development, Manufacturing, and Commercialization.*

*TREAT shall study the economic feasibility of manufacturing psychedelic medicines to reduce the cost of psychedelic medicines to Californians and generate revenue for the State of California. If the Board determines it is economically feasible, TREAT may research, develop, and manufacture new psychedelic medicines and may hold any and all intellectual property rights therein, subject to consideration of ethical issues related to Native American, Indigenous, or other traditional use or practice.*

#### **152008. Standards.**

*TREAT shall promote ethical, inclusive, and sustainable practices in psychedelic medicine research and implementation, including equitable access to care for all Californians.*

*(a) Ethics, Accountability, and Inclusivity*

*TREAT shall develop, enforce, and evaluate the effectiveness of ethical standards to protect research participant and patient rights, prevent conflicts of interest, promote inclusivity, protect the environment, and ensure that research and therapy delivery funding is spent in a manner that advances the purposes of the Act, including, but not limited to:*

*(1) Standards to promote the accessibility and affordability of therapies arising from TREAT-funded research for all Californians, regardless of economic means, through engagement with health care providers, research and therapy development institutions, businesses, governmental agencies, philanthropists, foundations, and patient advocacy groups, and based on recommendations made by the any and all appropriate working groups. These standards shall specifically ensure that care is extended to underserved communities, and that these communities are represented in TREAT's decision-making processes.*

*(2) Policies to prevent conflicts of interest within TREAT and with external partners, including establishing an independent review process to assess potential conflicts.*

*(3) Standards to protect the rights and welfare of research participants through rigorous Institutional Review Boards and informed consent processes. Standards for obtaining the informed consent of research participants shall initially be generally based on the standards for research funded by the National Institutes of Health, with modifications to adopt to the Institute's mission and objectives.*

*(4) Standards for the review of research involving human subjects, which initially shall be generally based on the Institutional Review Board standards promulgated by the National Institutes of Health, with modifications to adapt to the Institute’s mission and objections.*

*(5) Standards for the design and conduct of clinical trials, including:*

*(i) Standards to ensure that clinical trials include diverse research participants.*

*(ii) Standards to ensure that clinical trials comply with applicable state and federal laws, including, without limitations, all applicable privacy laws.*

*(iii) Standards for tracking laboratory results, scans, and panomics (including genomics, transcriptomics, proteomics and metabolomics) in a socially responsible manner and based on best practices established by the National Academy of Sciences.*

*(iv) Standards to ensure that funding for research is stopped if awardees do not meet prescribed milestones or if research is deemed to be unsafe or ineffective.*

*(6) Standards prohibiting compensation to research participants, which permit reimbursement of expenses, including lost wages arising from research participation.*

*(7) Standards permitting reimbursement for expenses, which shall include but not be limited to medical expenses and lodging, meals, and travel expenses for research participants and caregivers, and childcare for research participants, in order to ensure functional access to clinical trials. For the purposes of this paragraph “caregivers” includes family members, friends, and professional caregivers providing supportive care to research participants.*

*(8) Standards for the development of objective metrics for assessing clinical outcomes, including identifying metrics to measure patients’ wellbeing and risk stratification, the economic burden caused by mental health conditions and health disorders that may be treated with psychedelic medicines, and the cost efficiencies of psychedelic therapies compared to other forms of treatment.*

*(9) Environmental policies and guidelines for the sourcing of psychedelic medicines that protect endangered plants and minimize TREAT’s environmental impact.*

*(10) In consultation with religious, Native American, and Indigenous leaders, TREAT shall establish cultural standards to ensure conservation of endangered or threatened medicines and to protect traditional practices, cultural knowledge, and medicines.*

*(11) Standards to require the administration of TREAT-funded psychedelic medicines in a supervised setting and to restrict the distribution of TREAT-funded psychedelic medicines at pharmacies or dispensaries until longitudinal data is available regarding the safety and efficacy of psychedelic medicines and the optimal modalities for administration of psychedelic medicines.*

*(b) Regulations and Oversight. TREAT shall seek to establish strong relationships with oversight bodies and regulatory agencies to advocate for legislative and policy changes that*



*advance the purposes of the Act, including advocating for policies that protect employees from adverse action based on their participation in clinical trials involving psychedelic medicines.*

**152009. Economics.**

*TREAT shall track its costs and assess the economic impacts of its initiatives.*

*(a) Economic Burden by Condition*

*(1) TREAT shall partner with state agencies and independent experts to conduct a comprehensive, multi-faceted analysis of the economic burden of relevant diseases, considering both direct and indirect costs.*

*(2) TREAT shall conduct comparative studies to analyze the costs of psychedelic therapies versus existing paradigms.*

*(3) TREAT shall explore the inclusion of wellbeing as a metric in evaluations.*

*(4) TREAT shall seek to collaborate with state agencies and experts to develop clear, agreed-upon metrics for assessing the economic impact of psychedelic therapies.*

*(5) TREAT shall invest in developing state-of-the-art methods for monitoring these metrics.*

*(b) Economic Benefits*

*TREAT shall monitor and report to the public regarding its program expenses, revenue, and the impact of its programs on job creation.*

*(c) In-House Manufacturing*

*TREAT shall analyze the costs and benefits of developing and manufacturing psychedelic medicines and psychedelic therapies in-house and may implement this program if it determines it the benefits outweigh the costs.*

**152010. Creation of the Oversight Board.**

*There is hereby created the TREAT Oversight Board, hereinafter, the Board, which shall govern the Institute and is hereby vested with full power, authority, and jurisdiction over the Institute.*

**152011. Board Membership; Appointments; Terms of Office.**

*(a) Board Membership*

*The Board shall have seven members, appointed as follows:*

*(1) The Governor shall appoint a member who has demonstrated experience designing, funding, and running clinical trials and overseeing the administration of scientific or medical research grants, including basic research and clinical trials. The member appointed by the Governor shall have the following qualifications and experience:*

*(A) Experience serving on the boards of organizations, preferably within a research-focused organization.*

*(B) Significant experience in high-level leadership positions within one or more research organizations.*

*(C) Experience disseminating research findings, advocating for research interests, and fostering collaboration among researchers and practitioners.*

*(D) Experience in the health sector with clinical trials and basic research, including experience with risk stratification, wellbeing, and bioinformatics.*

*(E) Experience in developing and implementing policies and procedures for governing research activities, including but not limited to policies related to funding allocation, research conduct and ethics, conflict of interest, data sharing, and research evaluation and accountability.*

*(F) One or more advanced degrees in a relevant field such as biology, genetics, medicine, or a related discipline.*

*(2) The Lieutenant Governor shall appoint a member with demonstrated expertise providing training and education to professionals in the field of mental health. The member appointed by the Lieutenant Governor shall have the following qualifications and experience:*

*(A) Experience serving on boards of organizations, particularly those focused on healthcare education and research.*

*(B) Experience leading and managing academic ventures effectively, with a successful track record of building academic programs from the ground up.*

*(C) Experience with the legal and regulatory guidelines relevant to training care providers, including ethics, privacy, and risk stratification.*

*(D) Participation in professional associations and communities in the field, and contributions to the development of accreditation guidelines for care providers.*

*(E) Experience in the field of psychedelic-assisted therapy, research, and education, including a deep knowledge in therapeutic and psychological sciences.*

*(F) One or more advanced degrees in medicine or psychology.*

*(G) A demonstrated commitment to mental healthcare and education.*

*(H) Experience with direct patient care, ideally treating clients with PTSD, depression, anxiety, addiction, or end-of-life distress, and experience applying psychedelic therapies in complex cases.*

*(I) Experience collaborating and integrating with existing private and public programs, and developing state, national, or international policy.*

*(3) The Treasurer shall appoint a member who has demonstrated experience in establishing or administering medical or mental health clinics in underserved communities, as well as experience establishing or developing insurance reimbursement programs and other methods to ensure access. The member appointed by the Treasurer shall have the following qualifications and experience:*

*(A) Experience serving on the boards of companies or organizations, particularly those focused on healthcare and fintech.*

*(B) Experience establishing successful and sustainable business models in biotechnology and healthcare.*

*(C) Experience in the scientific and business aspects of the healthcare, pharmaceutical, and biotechnology industries.*

*(D) Experience advocating for advancements in medicine and healthcare.*

*(E) Experience in the distribution of medicines, especially in a regulated environment.*

*(F) Experience in the management of clinics and healthcare facilities, including the implementation of operational and patient care standards.*

*(G) Experience in ensuring access to care, navigating reimbursement processes, and managing market access for healthcare products and services.*

*(H) One or more advanced degrees or the equivalent in business, fintech, pharmacogenomics, and personalized medicine.*

*(I) Experience in working with government agencies, philanthropic organizations, and private donors to secure grants and donations.*

*(4) The Attorney General shall appoint a member with a history of establishing and overseeing innovative large-scale data and technology projects, including biobanking, bioinformatics, and digital health applications. The member appointed by the Attorney General shall have the following qualifications and experience:*

*(A) Experience serving on the boards of a variety of organizations, particularly those focused on healthcare and health technology.*

*(B) Knowledge and experience with convergent exponential technologies, data liquidity, and other aspects of health information technology.*

*(C) Experience leading and managing entrepreneurial ventures effectively.*

*(D) Experience in compliance with relevant legal and regulatory guidelines, and with the ethical practice, privacy, and security in the use of technology and data in healthcare.*

*(E) Experience managing substantial budgets and large-scale information technology programs.*

*(F) Experience in the data and technology aspects of the healthcare, pharmaceutical, and biotechnology industries.*

*(G) One or more advanced degrees in medicine, science, or technology.*

*(H) Experience collaborating and integrating with existing private and public programs, and developing state, national, or international policy.*

*(5) The Controller shall appoint a member with expertise and experience in public-private partnerships including in intellectual property and equity investment.*

*The member appointed by the Controller shall have the following qualifications and experience:*

*(A) Experience serving on the boards of biotechnology companies.*

*(B) Experience leading and managing both academic and entrepreneurial ventures.*

*(C) Experience establishing successful and sustainable business models in biotechnology.*

*(D) Experience in the scientific and business aspects of the healthcare, pharmaceutical, and biotechnology industries.*

*(E) Experience with the development of therapeutics and diagnostics to improve patient outcomes.*

*(F) Experience in working with government agencies, philanthropic organizations, and private donors to secure grants, donations, or funding for large-scale initiatives.*

*(6) The Board may request that up to five additional members be nominated, subject to the Board's confirmation.*

*(A) If the Board requests one additional member, the Governor shall nominate a member within 60 days of the request.*

*(B) If the Board requests a second additional member, the Lieutenant Governor shall nominate a member within 60 days of the request.*

*(C) If the Board requests a third additional member, the Treasurer shall nominate a member within 60 days of the request.*

*(D) If the Board requests a fourth additional member, the Attorney General shall nominate a member within 60 days of the request.*

*(E) If the Board requests a fifth additional board member, the Controller shall nominate a member within 60 days of the request.*

*(F) An individual nominated by a constitutional officer pursuant to subparagraphs (A) through (E) of this paragraph shall be seated as a member upon confirmation by the Board.*

*(7) A chairperson and vice chairperson shall be elected by the members. Within 45 days of the effective date of this Act, the Governor, Lieutenant Governor, Treasurer and Attorney General shall each nominate a candidate for chairperson and another candidate for vice chairperson.*

*(A) The chairperson of the Board shall meet the following criteria:*

*(i) Experience with serving on boards of organizations, understanding board governance principles, and collaborating with board members to drive organizational objectives.*

*(ii) Experience managing multi-billion-dollar budgets.*

*(iii) A demonstrated ability to lead and manage organizations effectively, with a track record of successful leadership positions.*

*(iv) Extensive knowledge and experience in the healthcare and medical research field, with expertise in psychedelic therapies, the operations of state funding agencies, and a successful record in clinical trial research and approvals of therapies.*

*(v) Experience securing funding and managing large-scale research initiatives.*

*(vi) Experience working with government agencies, philanthropic organizations, and private donors to secure grants and donations.*

*(vii) Experience in advocating for causes, initiatives, and policies related to healthcare and medical research.*

*(viii) One or more advanced degrees in a relevant field such as medicine, life sciences, business administration, or a related discipline.*

*(B) The vice chairperson of the Board shall meet the following criteria:*

*(i) Experience leading organizations that work with large government agencies and statewide or national organizations.*

*(ii) Experience in governance, training, and field mobilization, national issue campaigns, and state and local policy advocacy.*

*(iii) Experience in strategic planning and policy direction, large-scale operational planning, and the integration of all elements of national power, including diplomatic, economic, informational, and military components.*

*(iv) Experience in advocating effectively for policy change related to healthcare and other rights.*

*(v) Experience in public engagement, including giving oral and written testimonials to governmental agencies and the public.*

*(vi) Experience in launching and managing political, legislative, and community mobilization campaigns both in the U.S. and globally.*

*(vii) Experience complementary to the chairperson.*

*(viii) Experience leading social service delivery organizations committed to improving the wellbeing of others.*

*(C) Additional Criteria: A candidate for vice chairperson with the following qualifications will be preferred:*

*(i) Service in the armed forces.*

*(ii) A candidate who is fluent in languages other than English.*

*(iii) Experience in leading initiatives aimed at Spanish-speaking communities.*

*(8) In addition to the criteria contained in paragraphs (1), (2), (3), (4), (5), and (7) of this subdivision, all members of the Board shall meet the following criteria:*

*(A) Have struggled with mental health or have family members that have struggled with mental health;*

*(B) Experience serving on public, corporate, or nonprofit boards, particularly those focused on healthcare and health technology, with a comprehensive understanding of board governance principles.*

*(C) A commitment to understanding and applying psychedelic medicines to treat mental health and to the mission of TREAT.*

*(D) A commitment to expanding care for the underserved, providing patient-centric care, and improving access to health care in rural and urban settings.*

*(E) Proven ability to build and maintain professional relationships and collaborate with diverse stakeholders across the academic, entrepreneurial, and government spectrums, and a commitment to build collegial and collaborative relationships within TREAT.*

*(F) Not be employed by an awardee at the time of their appointment and throughout the tenure of their service on the Board.*

*(b) Appointment of Board Members.*

*(1) All appointments pursuant to paragraphs (1) through (5) of subdivision (a) shall be made within 90 days of the effective date of this act. If any of the appointments are not completed within the permitted time frame, the Board shall proceed to operate with the appointments that are in place, provided that at least 60 percent of the appointments have been made.*

*(2) Ninety days after the effective date of the measure adding this chapter, the State Controller and the Treasurer, or if only one is available within ninety days, the available one, shall convene a meeting of the appointed members of the Board to elect a chairperson and vice chairperson from among the individuals nominated by the constitutional officers pursuant to paragraph (7) of subdivision (a).*

*(c) Board Member Terms of Office*

*(1) The members appointed or elected pursuant to subdivision (a) shall serve eight-year terms. Members shall serve a maximum of two consecutive terms, unless earlier removed pursuant to paragraph (4).*

*(2) If a vacancy occurs within a term, the appointing authority shall appoint a replacement member within 90 days to serve the remainder of the term. If a replacement member has been appointed to serve less than half of a remaining term, the member shall be eligible to serve two additional consecutive terms.*

*(3) When a term expires, the appointing authority shall appoint a member within 90 days. Board members shall continue to serve until their replacements are appointed.*

*(4) The Board may remove a member from the Board by a majority vote of all of the members of the Board, with the exception of the member whose removal is under consideration.*

**152012. Majority Vote of Quorum.**

*Except as otherwise specified, all actions of the Board shall be taken by a majority vote of a quorum of the Board.*

**152013. Board Functions.**

*(a) The Board shall perform the following functions:*

*(1) Oversee the operations of the Institute.*

*(2) Develop annual and long-term strategic research and financial plans for the Institute.*

*(3) Make final decisions on standards to govern the activities covered by the Act.*

*(4) Issue requests for proposals for funding and make final decisions on grant, loan, and investment awards for basic research; clinical trials; therapy development, delivery, accessibility, and affordability; training and education; facilities; and other award programs deemed necessary by the Board to accomplish the Institute's mission.*

*(5) Ensure the completion of an annual financial audit of the Institute's operations and the triennial performance audit.*

*(6) Issue public reports on the Institute's activities, including economic and health impact reports.*

*(7) Hold an annual conference for the public to highlight research results, training programs, access to care, and psychedelic therapies. The Institute may reimburse the expenses of, and pay a reasonable honorarium to, speakers, including research participants, who address the conference.*

*(8) Establish policies regarding intellectual property rights arising from Institute-funded research, in accordance with Section 152028.*

*(9) Establish rules and guidelines for the operation of the Board and its working groups.*

*(10) Select the members of the working groups, in accordance with Section 152017.*

*(11) Adopt, amend, and rescind rules and regulations to carry out the purposes and provisions of this chapter, and to govern the procedures of the Board. Except as provided in paragraph (1) of subdivision (b), these rules and regulations shall be adopted in accordance with the Administrative Procedure Act (Government Code, Title 2, Division 3, Part 1, Chapter 3.5, Sections 11340 et seq.).*



*(12) Request the issuance of bonds from the California Psychedelic Research Finance Committee and loans from the Pooled Money Investment Board.*

*(13) Approve the annual budget for the Institute, and in the first five years, budget to ensure that the Institute's activities are revenue-positive for the State of California during its first five years of operation without jeopardizing the progress of its research program.*

*(b) The Board is authorized to perform the following functions:*

*(1) Notwithstanding the Administrative Procedure Act (APA), and in order to facilitate the immediate commencement of research covered by this Act, the Board may adopt interim regulations without compliance with the procedures set forth in the APA. The interim regulations shall remain in effect for 270 days unless earlier superseded by regulations adopted pursuant to the APA.*

*(2) Notwithstanding Section 11005 of the Government Code, accept additional revenue and real and personal property, including, but not limited to, gifts, royalties, interest, capital stock, and appropriations that may be used to supplement annual research grant funding and the Institute's operations.*

*(3) Perform all other acts necessary or appropriate in the exercise of its power, authority, and jurisdiction over the Institute.*

**152014. Board Operations.**

*(a) Legal Actions and Liability*

*(1) The Institute may sue and be sued.*

*(2) Based upon standards adopted by the Board, Institute awardees shall indemnify or insure and hold the Institute and its Directors and Officers harmless against any and all losses, claims, damages, expenses, or liabilities, including attorneys' fees, arising from research conducted by the awardee pursuant to the award.*

*(3) Given the scientific, medical, and technical nature of the issues facing the Board, and notwithstanding Section 11042 of the Government Code, the Institute is authorized to retain outside counsel when the Board determines that the Institute requires specialized services not provided by the Attorney General's office.*

*(4) The Institute may enter into any contracts or obligations which are authorized or permitted by law.*

**152015. Institute Personnel.**

*(a) The Board shall from time to time determine the total number of authorized employees for the Institute.*

*(b) The Board shall select a chairperson and vice chairperson as specified by paragraph (2) of subdivision (b) of Section 152011, who shall exercise all of the powers delegated to them by the Board.*

*(c) The following functions apply to the chairperson and vice chairperson:*

*(1) The chairperson's primary responsibilities are to manage the Board agenda and workflow including all evaluations and approvals of awards and standards, and to supervise all annual reports; to interface with the California Legislature, the United States Congress, the California health care system, and the California public; and to optimize all financial leverage opportunities for the Institute. The chairperson shall also serve as a member of the Clinical Trials and Research Working Group, the Care Provider Training Working Group, and such other working groups as the Board may establish.*

*(2) The vice chairperson's primary responsibilities are to support the chairperson in all duties and to carry out those duties in the chairperson's absence.*

*(d) Each member of the Board shall be a full-time employee of the Institute and shall perform an operational role within the Institute. Each Board Member shall be compensated for their service as determined by the California Citizens Compensation Commission.*

*(e) The Board shall establish daily consulting rates and expense reimbursement standards for the non-Board members of all Institute working groups.*

*(f) Notwithstanding Section 19825 of the Government Code, the Board shall set compensation for the Institute's scientific, medical, technical, and administrative staff within the range of compensation levels for executive officers and scientific, medical, technical, and administrative staff of medical schools within the University of California system.*

**152016. Institute Divisions.**

*(a) The Institute shall have the following divisions:*

*(1) The Clinical Trials and Research Division, which shall be responsible for conducting the programs described in Section 152003. The Clinical Trials and Research Division shall be led by the member appointed pursuant to paragraph (1) of subdivision (a) of Section 152011.*

*(2) The Education Division, which shall be responsible for conducting the programs described in Section 152004. The Education Division shall be led by the member appointed pursuant to paragraph (2) of subdivision (a) of Section 152011.*

*(3) The Access Division, which shall be responsible for conducting the programs described in Section 152005. The Access Division shall be led by the member appointed pursuant to paragraph (3) of subdivision (a) of Section 152011.*

*(4) The Technology Division, which shall be responsible for conducting the programs described in Section 152006. The Technology Division shall be led by the member appointed pursuant to paragraph (4) of subdivision (a) of Section 152011.*

*(5) The Industry Division, which shall be responsible for conducting the programs described in Section 152007. The Industry Division shall be led by the member appointed pursuant to paragraph (5) of subdivision (a) of Section 152011.*

*(b) The Board may establish additional divisions as it deems necessary and appropriate to advance the purposes of the Act.*

**152017. Institute Working Groups.**

*(a) The Institute shall establish the Clinical Trials and Research Working Group and the Care Provider Training Working Group.*

*(b) The Board may establish additional working groups as it deems necessary and appropriate to advance the purposes of the Act. Such additional working groups shall have such membership and such duties as the Board shall determine.*

*(c) Appointments of working group members shall be made by the Board, within 180 days of the election of the chairperson and vice chairperson. In addition to members of the Board, working groups shall be composed of experts in their fields, advocates, and stakeholders and should reflect a diversity of experience and backgrounds. The non-Board working group members' terms shall be six years. The Board may, by a vote of 60 percent of a quorum, remove a non-Board working group member at any time.*

*(d) Each working group shall hold meetings as the Board deems necessary and appropriate to achieve the purposes and objectives of the working group.*

*(e) Recommendations of each of the working groups may be forwarded to the Board only by a vote of a majority of a quorum of the members of each working group. The Board shall consider the recommendations of the working groups in making its decisions on applications for awards and in adopting standards. The Board shall establish rules, procedures, and practices for each working group.*

***(f) Conflict of Interest***

*(1) The Board shall adopt conflict of interest rules, based on best practices, to govern the participation of non-Board working group members.*

*(2) The Board shall appoint an ethics officer from among the Institute's staff who shall serve as an ethics officer for the Institute and the working groups.*

*(3) Non-Board members of the working groups shall not be considered public officials, employees, or consultants for purposes of the Political Reform Act (Title 9 (commencing with*

*Section 81000) of the Government Code), Sections 1090 and 19990 of the Government Code, and Sections 10516 and 10517 of the Public Contract Code.*

*(g) Working Group Records*

*All records of the working groups submitted as part of the working groups' recommendations to the Board for approval shall be subject to the Public Records Act, Division 10 commencing with Section 7920.000) of Title 1 of the Government Code. Except as provided in this subdivision, the working groups shall not be subject to the provisions of the Bagley-Keene Open Meeting Act, Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code, or the Public Records Act.*

***152018. Clinical Trials and Research Working Group.***

*(a) Membership. The Clinical Trials and Research Working Group shall have at least 18 members as follows:*

*(1) The member described in paragraph (1) of subdivision (a) of Section 152011.*

*(2) At least 15 scientists or clinicians who have experience in the field of psychedelic research or mental health, at least 10 of whom shall serve on each expert peer review panel.*

*(3) The chairperson and the vice chairperson.*

*(b) Functions. The Clinical Trials and Research Working Group shall perform the following functions:*

*(1) Propose and fund clinical trials to be carried out at existing research institutions or contract research organizations.*

*(2) Recommend to the Board interim and final programmatic focus areas, criteria, standards, and requirements for considering funding applications and for awards.*

*(3) Recommend to the Board standards for the scientific and medical oversight of awards, including standards to ensure that funding for research is stopped if awardees do not meet prescribed milestones or if research is deemed to be unsafe or ineffective.*

*(4) Recommend to the Board any modifications of the criteria, standards, and requirements described in paragraphs (1) and (2) above as needed.*

*(5) Review applications for awards based on the criteria, requirements, and standards adopted by the Board and make award recommendations to the Board.*

*(6) Conduct peer group progress oversight reviews of awardees to ensure compliance with the terms of the award, and report to the Board any recommendations for subsequent action.*

*(7) Recommend to the Board standards for the evaluation of awardees to ensure that they comply with all applicable requirements. Such standards shall mandate periodic reporting by awardees and shall authorize the Clinical Trials and Research Working Group to audit an awardee and forward any recommendations for action to the Board.*

*(c) Recommendations for Awards. Award recommendations shall be based upon a competitive evaluation. Only the scientist or clinician members of the Clinical Trials and Research Working Group appointed pursuant to paragraph (2) of subdivision (a) shall score award applications for scientific merit. Such scoring shall be based on scientific merit including the following:*

*(1) The experience and qualifications of the applicant team.*

*(2) The quality of the research proposal, the potential for achieving significant research or clinical results, the timetable for realizing such significant results, the importance of the research objectives, and the innovativeness of the proposed research.*

*(3) Whether the research is proposed to be conducted in California, and if not, whether the research would benefit the citizens of California.*

*(4) The cost effectiveness of the proposed research.*

**152019. Care Provider Training Working Group.**

*(a) Membership*

*The Care Provider Training Working Group shall have 9 members as follows:*

*(1) The chairperson and vice chairperson of the Board and the member described in paragraph (2) of subdivision (a) of Section 152011.*

*(2) One member with experience running an academic or nonprofit training program.*

*(3) One member who is an educator in the field of mental health.*

*(4) One member who is a student in the field of mental health.*

*(5) One member who is a practicing care provider.*

*(6) One member who is a member of an indigenous or tribal community with experiences in traditional plant medicine or indigenous medicine practices; and*

*(7) One member who is a religious leader with experience in psychedelic research.*

*(b) Functions*

*The Care Provider Training Working Group shall have the following functions:*

*(1) Recommend to the Board standards and curricula for the education, training, certification, and oversight of care providers in psychedelic-assisted therapy and other psychedelic therapies.*

*(2) Recommend to the Board interim and final criteria, standards, and requirements for considering funding applications and for making awards for the education and training of care providers in psychedelic-assisted therapy and other psychedelic therapies.*

*(3) Recommend to the Board standards for the oversight of education and training awards.*

*(4) Review award applications based on the criteria, requirements, and standards adopted by the Board and make recommendations to the Board for the award of education and training awards.*

*(5) Conduct peer group progress oversight reviews of education and training awardees to ensure compliance with the terms of the award, and report to the Board any recommendations for subsequent action.*

*(6) Recommend to the Board standards for the evaluation of awardees to ensure that they comply with all applicable requirements. Such standards shall mandate periodic reporting by awardees and shall authorize the Care Provider Training Working Group to audit an awardee and forward any recommendations for action to the Board.*

*(c) Recommendations for Awards*

*Award recommendations shall be based upon a competitive evaluation. Only the non-Board members of the working group shall score grant applications for merit. Such scoring shall be based on merit including the following:*

*(1) The experience and qualifications of the applicant.*

*(2) The quality of the education or training proposal, the potential for achieving significant results, the timetable for realizing such significant results, and the importance of the education or training objectives.*

*(3) The cost effectiveness of the proposed training or education program.*

***152020. Appropriation and Allocation of Funding.***

*(a) Moneys in the California Psychedelic Research Fund shall be allocated as follows:*

*(1) No less than 94 percent of the proceeds of the bonds authorized pursuant to Section 152035, shall be used for research and therapy delivery funding.*

*(2) No more than 6 percent of the proceeds of the bonds authorized pursuant to Section 152035 shall be used for the costs of general administration of the Institute.*

*(3) The Board shall limit indirect costs to 25 percent of each award, excluding amounts included in a facilities award, except that the indirect cost limitation may be increased by that amount by which an awardee provides matching funds in excess of 20 percent of the award amount.*

*(b) To enable the Institute to commence operating during the first six months following the adoption of the measure adding this chapter, there is hereby appropriated from the General Fund as a temporary start-up loan to the Institute six million dollars (\$6,000,000) for initial administrative and implementation costs. All loans to the Institute pursuant to this appropriation shall be repaid to the General Fund from the proceeds of bonds sold pursuant to Section 152035 within 12 months of the start of said bond sales.*

*(c) If the State is unable to issue bonds in the first fiscal year following passage of the Act, one hundred and fifty million dollars (\$150,000,000) is hereby appropriated from the General Fund as a loan to the Institute to fund the implementation of the Act and annually thereafter until bonds are sold. All loans to the Institute pursuant to this appropriation shall be repaid to the General Fund from the proceeds of bonds sold pursuant to Section 152035 within 12 months of the start of said bond sales.*

**152021. Annual Public Report.**

*The Institute shall issue an annual report to the public which sets forth its activities, awards, awards in progress, accomplishments, and future program directions. Each annual report shall include, but not be limited to, the following: the number and dollar amounts of awards; the awardees for the prior year; the Institute's administrative expenses; an assessment of the availability of funding for psychedelic research from sources other than the Institute; a summary of research findings, including promising new research areas; an assessment of the relationship between the Institute's awards and its goals and the overall strategy of its program; and a report of the Institute's strategic research and financial plans.*

**152022. Annual Audit and Triennial Performance Audit.**

*(a) The Institute shall annually commission an independent financial audit of its activities from a certified public accounting firm, which shall be provided to the State Controller, who shall review the audit and shall annually issue a public report of that review.*

*(b) The Institute shall commission a performance audit every three years beginning with the audit for the 2027–28 fiscal year. The performance audit, which may, at the discretion of the Board, be performed by the Bureau of State Audits or an independent audit firm, shall examine the functions, operations, management systems, and policies and procedures of the Institute to assess whether the Institute is achieving economy, efficiency, and effectiveness in the deployment of available resources. The performance audit shall be conducted in accordance with government auditing standards, and shall include a review of whether the Institute is complying with Board policies and procedures. The performance audit shall not be required to include a review of scientific performance. The performance audit shall include, but not be limited to, all of the following:*

*(1) Policies and procedures for the issuance of awards and a review of a representative sample of awards executed by the Institute.*

*(2) Policies and procedures relating to the protection or treatment of intellectual property rights associated with research funded by the Institute.*

*(c) All administrative costs of the audits required by this section shall be paid by the Institute.*

*(d) In the event that the triennial performance audit required by paragraph (b) of this section identifies failures or areas requiring improvement, the Institute shall develop a remediation plan within 90 days and shall present it to the Board at its next regularly scheduled meeting following that date.*

### **152023. Citizens' Financial Accountability Oversight.**

*There shall be a Citizens' Financial Accountability Oversight Committee chaired by the State Controller. This committee shall review the annual financial audit, the State Controller's report and evaluation of that audit, and the financial practices of the Institute. The State Controller, the State Treasurer, the President pro Tempore of the Senate, the Speaker of the Assembly, and the Chairperson of the Board shall each appoint a public member of the committee. Committee members shall have medical research, patient advocacy, or financial experience. The committee shall provide recommendations on the Institute's financial practices and performance. The State Controller shall provide staff support to the committee. The committee shall hold a public meeting, with appropriate notice, and with a formal public comment period. The committee shall evaluate public comments and include appropriate summaries in an annual report. The Board shall provide funds for the per diem expenses of the committee members and for publication of the annual report.*

### **152024. Public Meeting Laws.**

*(a) The Board shall hold at least two public meetings per year, one of which will be designated as the Institute's annual meeting. The Board may hold additional meetings as it determines are necessary or appropriate.*

*(b) The Bagley-Keene Open Meeting Act, Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code, shall apply to all meetings of the Board, except as otherwise provided in this section. The Board shall make all awards in public meetings and shall adopt all governance, scientific, medical, and regulatory standards in public meetings.*

*(c) The Board may conduct closed sessions as permitted by the Bagley-Keene Open Meeting Act, under Section 11126 of the Government Code. In addition, the Board may conduct closed sessions when it meets to consider or discuss:*

*(1) Matters involving information relating to patients or medical subjects, the disclosure of which would constitute an unwarranted invasion of personal privacy.*



*(2) Matters involving confidential intellectual property, trade secrets, or work product, whether patentable or not, including, but not limited to, any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information, which is not patented, which is known only to certain individuals who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know it or use it.*

*(3) Matters involving prepublication, confidential scientific research or data.*

*(4) Matters concerning the appointment, employment, performance, compensation, or dismissal of Institute employees, provided that action on compensation of the Institute's employees shall only be taken in open session.*

*(c) The meeting required by paragraph (2) of subdivision (b) of Section 152011 shall be deemed to be a special meeting for the purposes of Section 11125.4 of the Government Code.*

*(d) The Bagley-Keene Open Meeting Act shall only apply to Board Members acting in their capacity as Board Members and shall not apply to Board Members acting in their capacity as employees performing an operational role within the Institute or acting as members of a working group.*

**152025. Public Records.**

*(a) The California Public Records Act, Division 10 of Title 1 of the Government Code (commencing with Section 7920.000), shall apply to all records of the Institute, except as otherwise provided in this section.*

*(b) Nothing in this section shall be construed to require disclosure of any records that are any of the following:*

*(1) Personnel, medical, or similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy.*

*(2) Records containing or reflecting confidential intellectual property or work product, whether patentable or not, including, but not limited to, any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information, which is not patented, which is known only to certain individuals who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know it or use it.*

*(3) Prepublication scientific working papers or research data, including, but not limited to, applications for funding and awardee progress reports.*

**152026. Competitive Bidding.**

*(a) The Institute shall, except as otherwise provided in this section, be governed by the competitive bidding requirements applicable to the University of California, as set forth in Article 1 through 5 (commencing with Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the Public Contract Code.*

*(b) For all Institute contracts, the Board shall follow the procedures required of the Regents by Articles 1 through 5 (commencing with Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the Public Contract Code with respect to contracts let by the University of California.*

*(c) The requirements of this section shall not be applicable to awards approved by the Board.*

*(d) Except as provided in this section, the Public Contract Code shall not apply to contracts let by the Institute.*

**152027. Conflicts of Interest.**

*(a) The Political Reform Act, Title 9 (commencing with Section 81000) of the Government Code, shall apply to the Institute and to the Board, except as provided in this section and in subdivision (f) of Section 152017.*

*(1) A member of the Board may participate in a decision to approve an award or a contract to an entity for the purpose of research involving a mental health condition or health disorder from which a member or the member's immediate family suffers.*

*(2) The adoption of standards, including, but not limited to, strategic plans, concept plans, and research budgets is not subject to the conflict of interest provisions of the Political Reform Act or Government Code section 1090.*

*(b) Section 1090 of the Government Code shall not apply to any award or contract made by the Board except where both of the following conditions are met:*

*(1) The award or contract directly relates to goods or services to be provided by any member of the Board, or financially benefits the member.*

*(2) The member fails to recuse themselves from making, participating in making, or in any way attempting to use the member's official position to influence a decision on the award or contract.*

**152028. Patent Royalties and License Revenues Paid to the State of California.**

*(a) The Board shall establish standards that require that all awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from research funded by the Institute with the need to*

*ensure that essential research is not unreasonably hindered by the intellectual property agreements.*

*(b) The standards established pursuant to subdivision (a) shall include, at a minimum, a requirement that Institute awardees, other than loan recipients, facilities grant recipients and awardees who have agreed to an alternative value-sharing mechanism, such as equity, share a fraction of the revenue they receive from licensing or self-commercializing an invention or technology that arises from research funded by the Institute.*

*(c) For the first fifteen years of TREAT's existence, all royalty revenues received through the intellectual property agreements established pursuant to this section shall be deposited into the California Psychedelic Research Fund and may be used for any purpose set forth in Section 152020, including but not limited to the TREAT Institute's administrative expenses. Beginning in the sixteenth year of TREAT's existence, five percent of all royalty revenues received through the intellectual property agreements established pursuant to this section shall be deposited into the General Fund, and ninety-five percent shall be deposited in the California Psychedelic Research Fund. For the next four years thereafter, the percentage of royalty revenues received through the intellectual property agreements established pursuant to this section and deposited in the General Fund shall increase by five percent until twenty-five percent of the royalty revenues received through the intellectual property agreements established pursuant to this section are allocated to the General Fund and seventy-five percent are allocated to the California Psychedelic Research Fund on an annual basis.*

*(d) Any revenues obtained through alternative value-sharing mechanisms shall be deposited into the California Psychedelic Research Fund and may be used for any purpose set forth in Section 152020, including but not limited to the TREAT Institute's administrative expenses.*

**152029. Preference for California Suppliers.**

*The Board shall establish standards to ensure that awardees purchase goods and services from California suppliers to the extent reasonably possible, in a good faith effort to achieve a goal of more than 50 percent of such purchases from California suppliers.*

**152030. Medical and Scientific Accountability Standards.**

*In order to avoid duplication or conflicts in technical standards for scientific and medical research, with alternative state programs, the Institute will develop its own scientific and medical standards to carry out the specific controls and intent of the Act, notwithstanding any other current or future state laws or regulations dealing with the study and research of psychedelic medicines. The Board, the Institute's working groups, and the Institute's awardees shall be governed solely by the provisions of this Act in the establishment of standards, the making of awards, and the conduct of awardees pursuant to this Act.*

## **Chapter 2. TREAT California NOW Bond Act of 2024**

### **152031.**

*This chapter shall be known, and may be cited, as the TREAT California NOW Bond Act of 2024.*

### **152032.**

*As used in this chapter, the following terms have the following meaning:*

*(a) “Act” means the “TREAT California Act.”*

*(b) “Committee” means the California Psychedelic Research Finance Committee created pursuant to subdivision (a) of Section 152037.*

*(c) “Fund” means the California Psychedelic Research Fund created pursuant to Section 152034.*

*(d) “Interim debt” means any interim loans pursuant to subdivisions (b) and (c) of Section 152020, Sections 152041 and 152042, bond anticipation notes or commercial paper notes issued to make deposits into the fund and which will be paid from the proceeds of bonds (including bonds issued in the form of commercial paper notes) issued pursuant to this chapter.*

### **152033.**

*(a) Notwithstanding Section 13340 of the Government Code or any other provision of law, the moneys in the fund are appropriated without regard to fiscal years to the Institute for the purpose of:*

*(1) providing direct funding, grants, investments, or loans for research into psychedelic medicines and therapies and to provide the infrastructure to deliver these therapies to all who need them, all as described in and pursuant to the Act.*

*(2) paying general administrative costs of the Institute (not to exceed 6 percent of the net proceeds of each sale of bonds).*

*(3) paying the annual administration costs of the interim debt or bonds;*

*(4) paying the costs of issuing interim debt, and paying interest on interim debt, if such interim debt is incurred or issued on or prior to December 31 of the fifth full calendar year after this chapter takes effect.*

*(5) paying the costs of issuing bonds, and paying interest on bonds that accrues on or prior to December 31 of the fifth full calendar year after this chapter takes effect (except that such limitation does not apply to premium and accrued interest as provided in Section 152044).*

*(b) Moneys in the fund or other proceeds of the sale of bonds authorized by this chapter may be used to pay principal of or redemption premium on any interim debt issued prior to the issuance of bonds authorized by this chapter. Moneys deposited in the fund from the proceeds of interim debt may be used to pay the Institute's general administrative costs without regard to the 6 percent limit set forth in paragraph (2) of subdivision (a) of this section, so long as such 6 percent limit is satisfied with respect to the total amount of bonds authorized pursuant to Section 152035.*

*(c) Repayment of principal and interest on any loans made by the TREAT Institute pursuant to this chapter shall be deposited in the fund and used for the purposes set forth in Section 152020, including paying the TREAT Institute's administrative costs or for paying continuing costs of the annual administration of outstanding bonds.*

**152034.**

*The proceeds of interim debt and bonds (excluding any refunding bonds authorized pursuant to Section 152044) issued and sold pursuant to this chapter shall be deposited in the State Treasury to the credit of the California Psychedelic Research Fund, which is hereby created in the State Treasury.*

**152035.**

*Bonds in the total amount of five billion dollars (\$5,000,000,000), not including the amount of any refunding bonds issued in accordance with Section 152044, or as much thereof as is necessary, may be issued and sold to provide a fund to be used for carrying out the purposes expressed in this chapter and to be used and sold for carrying out the purposes of Section 152033 and to reimburse the General Obligation Bond Expense Revolving Fund pursuant to Section 16724.5 of the Government Code. The bonds, when sold, issued, and delivered shall be and shall constitute a valid and binding obligation of the State of California, and the full faith and credit of the State of California is hereby pledged for the punctual payment of both the principal of, and interest on, the bonds as the principal and interest become due and payable.*

**152036.**

*The bonds authorized by this chapter shall be prepared, executed, issued, sold, paid, and redeemed as provided in the State General Obligation Bond Law (Chapter 4 (commencing with Section 16720) of Part 3 of Division 4 of Title 2 of the Government Code), and all of the provisions of that law, as amended from time to time, except subdivisions (a) and (b) of Section 16727 of the Government Code apply to the bonds and to this chapter and are hereby incorporated in this chapter as though set forth in full in this chapter.*

**152037.**

*(a) Solely for the purpose of authorizing the issuance and sale, pursuant to the State General Obligation Bond Law, of the bonds and interim debt authorized by this chapter, the California Psychedelic Research Finance Committee is hereby created. For purposes of this chapter, the California Psychedelic Research Finance Committee is “the committee” as that term is used in the State General Obligation Bond Law. The committee consists of the Treasurer, the Controller, the Director of Finance, the Chairperson of the Institute, and two other members of the Board (as created by the Act) chosen by the Chairperson of the Institute, or their designated representatives. The Treasurer shall serve as chairperson of the committee. A majority of the committee may act for the committee.*

*(b) For purposes of the State General Obligation Bond Law, the Treatments Research Education Access & Therapies Institute is designated the “board.”*

**152038.**

*(a) Upon request of the Institute stating that funds are needed for purposes of the Act, the committee shall determine by resolution whether or not it is necessary or desirable to issue bonds authorized pursuant to this chapter in order to carry out the actions specified in this Act and, if so, the amount of bonds to be issued and sold. Successive issues of bonds may be authorized and sold to carry out those actions progressively, and it is not necessary that all of the bonds authorized to be issued be sold at any one time. The bonds may bear interest which is includable in gross income for federal income tax purposes. The costs of each bond issue sold on or after the 61st month after this article takes effect shall be at the discretion of the Treasurer and may be amortized over or up to a 40-year period.*

*(b) The total amount of the bonds authorized by Section 152035 that may be issued in any calendar year, commencing in 2025, shall not exceed five hundred million dollars (\$500,000,000). If less than this amount of bonds is issued in any year, the remaining permitted amount may be carried over to be issued in one or more subsequent years, provided that the amount issued in any one calendar year does not exceed the sum of five hundred million dollars (\$500,000,000) plus the amount of unused bond capacity carried over from one or more prior years. Pursuant to Section 152041, the Director of Finance may, in the director’s discretion, authorize a loan from the General Fund to the institute on or after the effective date of this article.*

*(c) Until December 31 of the fifth full calendar year after this section becomes effective, all interest on any interim debt or bonds issued under this article will be paid from proceeds from the sale of that interim debt or bonds in accordance with the objective of this initiative of avoiding any debt service payments by the General Fund, both principal and interest, during the initial period of basic research and therapy development following the effective date of this section.*

**152039.**

*There shall be collected each year and in the same manner and at the same time as other state revenue is collected, in addition to the ordinary revenues of the state, a sum in an amount required to pay the principal of, and interest on, the bonds. It is the duty of all officers charged by law with any duty regarding to the collection of the revenue to do and perform each and every act that is necessary to collect that additional sum.*

**152040.**

*Notwithstanding Section 13340 of the Government Code, there is hereby appropriated from the General Fund in the State Treasury, for the purposes of this chapter, an amount that will equal the total of the following:*

*(a) The sum annually necessary to pay the principal of, and interest on, bonds issued and sold pursuant to this chapter, as the principal and interest become due and payable.*

*(b) The sum necessary to carry out Section 152041 appropriated without regard to fiscal years.*

**152041.**

*For purposes of carrying out this chapter, the Director of Finance may authorize the withdrawal from the General Fund of an amount or amounts, not to exceed the amount of the unsold bonds that have been authorized by the committee, to be sold for the purpose of carrying out this article excluding any refunding bonds authorized pursuant to Section 152044, less any amount loaned pursuant to Section 152042 and not yet repaid, and any amount withdrawn from the General Fund pursuant to this section and not yet returned to the General Fund. Any amount withdrawn shall be deposited in the fund. Any money made available under this section shall be returned to the General Fund, plus an amount equal to the interest that the money would have earned in the Pooled Money Investment Account, from money received from the sale of bonds for the purpose of carrying out this chapter.*

**152042.**

*The Institute may request the Pooled Money Investment Board to make a loan from the Pooled Money Investment Account in accordance with Section 16312 of the Government Code for the purposes of carrying out this chapter. The amount of the request shall not exceed the amount of the unsold bonds that the committee, by resolution, has authorized to be sold for the purpose of carrying out this chapter, excluding any refunding bonds authorized pursuant to Section 152045, less any amount loaned pursuant to this section and not yet repaid, and any amount withdrawn from the General Fund pursuant to Section 152041 and not yet returned to the General Fund. The Institute shall execute any documents required by the Pooled Money Investment Board to obtain and repay the loan. Any amounts loaned shall be deposited in the fund to be allocated by the Institute in accordance with this chapter.*

**152043.**

*All money deposited in the fund that is derived from premium and accrued interest on bonds sold shall be reserved in the fund and shall be available for transfer to the General Fund as a credit to expenditures for bond interest, except that amounts derived from premium may be reserved and used to pay costs of issuance prior to any transfer to the General Fund.*

**152044.**

*The bonds issued and sold pursuant to this chapter may be refunded in accordance with Article 6 (commencing with Section 16780) of Chapter 4 of Part 3 of Division 4 of Title 2 of the Government Code, which is a part of the State General Obligation Bond Law. Approval by the voters of the state for the issuance of the bonds described in this chapter includes the approval of the issuance of any bonds issued to refund any bonds originally issued under this chapter or any previously issued refunding bonds. Any bond refunded with the proceeds of refunding bonds as authorized by this section may be legally defeased to the extent permitted by law in the manner and to the extent set forth in the resolution, as amended from time to time, authorizing that refunded bond.*

**152045.**

*Notwithstanding any provision of this chapter or the State General Obligation Bond Law, the Treasurer may maintain separate accounts for the investment of bond proceeds and for the investment earnings thereon. The Treasurer may use or direct the use of those proceeds or earnings to pay any rebate, penalty, or other payment required under federal law or take any other action with respect to investment and use of proceeds required or desirable under federal law to maintain the tax-exempt status of bonds and to obtain any other advantage under federal law on behalf of the funds of this state.*

**152046.**

*The proceeds from the sale of bonds authorized by this chapter are not “proceeds of taxes” as that term is used in Article XIII B of the California Constitution, and the disbursement of these proceeds is not subject to the limitations imposed by that article.*

**Chapter 3. Definitions**

**152047.**

*As used in this Division and in Article XXXVI of the California Constitution, the following terms have the following meanings:*

*(a) “Act” means the TREAT California Act constituting Chapters 1 through 3 (commencing with Section 152000) of Part 1 of Division 121 of the Health and Safety Code.*

*(b) “Award” means a grant, loan, guarantee, or investment.*



- (c) *“Awardee” means a recipient of an Award from the Institute.*
- (d) *“Basic research” means the investigation of basic mechanisms underlying the biology and chemistry of psychedelic medicines.*
- (e) *“Board” means the TREAT Oversight Board established pursuant to Section 152010 of the Health and Safety Code.*
- (f) *“Concomitant therapies” means therapies that, when administered along with a psychedelic therapy, increase the effectiveness of the therapy, and shall include, but not be limited to, meditation, yoga, transcutaneous magnetic stimulation, normobaric oxygen therapy, hyperbaric oxygen therapy, sound baths, tree bathing and other nature therapies, neuroarts, augmented reality, biofeedback nervous system regulators, and dance, art, music, and animal therapy.*
- (g) *“Constitutional officers” means the Governor, Lieutenant Governor, Attorney General, Treasurer, and Controller of California.*
- (h) *“Facilities” means buildings, building leases, or capital equipment.*
- (i) *“Fund” means the California Psychedelic Research Fund created pursuant to Section 152034.*
- (j) *“Health disorders” shall mean all physical health disorders that may be cured or treated with psychedelic therapies, including, but not limited to, pain, migraines, Alzheimer’s disease, and traumatic brain injury.*
- (k) *“Indirect costs” mean the recipient’s costs in the administration, accounting, general overhead, and general support costs for implementing an award of the institute. National Institutes of Health definitions of indirect costs will be utilized as one of the bases by the Clinical Trials and Research Working Group to create guidelines for awardees on this definition, with modifications to reflect guidance by the Board and this Act.*
- (l) *“Institute” means the Treatments Research Education Access and Therapies Institute. The Institute may also be referred to herein as “TREAT.”*
- (m) *“Interim regulations” means temporary regulations that perform the same function as “emergency regulations” under the Administrative Procedure Act (Government Code, Title 2, Division 3, Part 1, Chapter 3.5, Sections 11340 et seq.) except that in order to provide greater opportunity for public comment on the permanent regulations, remain in force for 270 days rather than 180 days.*
- (n) *“Mental health conditions” means all health conditions involving emotions, thinking or behavior, or a combination thereof, and shall include, and not be limited to, PTSD, anxiety, depression, addiction, and suicidality.*

(o) *“Psychedelic-assisted therapy” shall refer to the therapeutic use in which a patient is administered a psychedelic medicine under the supervision of a care provider, and shall include all preparatory sessions with the care provider preceding the administration of the psychedelic medicine and all integration sessions conducted after the administration of the psychedelic medicine.*

(p) *“Psychedelic medicines” shall refer to any substance or combination of substances, natural or synthetic, that produce altered states of consciousness, including, but not limited to, psilocybin, LSD, DMT, mescaline, LSD, ibogaine, MDMA, ketamine, cannabis, and similarly functioning substances.*

(q) *“Psychedelic therapies” shall have the same meaning as therapeutic uses.*

(r) *“PTSD” shall refer to post-traumatic stress disorder.*

(s) *“Quorum” means at least 65 percent of the members who are eligible to vote.*

(t) *“Research” shall refer to any scientific or medical study of the effects and potential therapeutic uses of psychedelic medicines, and shall include, but not be limited to, basic research and clinical trials.*

(u) *“Research and therapy delivery funding” includes funding for basic research, therapy development and delivery, and the development of psychedelic therapies through clinical trials, facilities, training and education, and accessibility and affordability programs, as provided in this division, and for the administration and oversight of the awards and programs, including the costs of the working groups, the costs associated with the expert review of applications; the costs of advisory groups and consultants established or retained to evaluate and advise the Board, the working groups, and awardees; and research conferences. When a facility’s grant or loan has not been provided to house all elements of the research, therapy development, and/or clinical trials, research funding shall include an allowance for a market lease rate of reimbursement for the facility. In all cases, operating costs of the facility, including, but not limited to, library and communication services, utilities, maintenance, janitorial, and security, shall be included as direct research funding costs. Legal costs of the Institute incurred in order to: negotiate standards with federal and state governments and research institutions; to implement standards or regulations; to resolve disputes; and/or to carry out all other actions necessary to defend and/or advance the Institute’s mission shall be considered research and therapy delivery funding costs.*

(v) *“Research participant” means a human enrolled with full disclosure and consent, and participating in clinical trials.*

(w) *“Revenue positive” means all state tax revenues generated directly and indirectly by the research and facilities of the Institute are greater than the debt service on the state bonds actually paid by the General Fund in the same year.*

*(x) “Therapeutic uses” shall refer to the use of psychedelic medicines as a treatment for mental health conditions or health disorders, or for the improvement of human wellbeing.*

SECTION 6. Section 20069 of the Government Code is amended to read:

(a) “State service” means service rendered as an employee or officer (employed, appointed or elected) of the state, the California Institute for Regenerative Medicine and the officers and employees of its governing body, *the Treatments Research Education Access & Therapies Institute and the members and employees of its governing body*, the university, a school employer, or a contracting agency, for compensation, and only while he or she is receiving compensation from that employer therefore, except as provided in Article 4 (commencing with Section 20990) of Chapter 11.

(b) “State service,” solely for purposes of qualification for benefits and retirement allowances under this system, shall also include service rendered as an officer or employee of a county if the salary for the service constitutes compensation earnable by a member of this system under Section 20638.

(c) “State service,” except for purposes of qualification for health or dental benefits, shall also include compensated service rendered by an officer, warrant officer, or a person of the enlisted ranks of the California National Guard who has elected to become a member pursuant to Section 20326 and who has not canceled his or her membership pursuant to Section 20327.

SECTION 7. Conformance with Federal Law.

Nothing in this Act shall permit the Institute to engage in activities that are prohibited by federal law.

SECTION 8. Severability.

If any provision of this act, or part thereof, is for any reason held to be invalid or unconstitutional, the remaining provisions shall not be affected, but shall remain in full force and effect, and to this end the provisions of this Act are severable.

SECTION 9. Amendments.

The statutory provisions of this measure, except the bond provisions, may be amended to enhance the Institute’s ability to further the purposes of the grant and loan programs created by the measure, by a bill introduced and passed no earlier than the third full calendar year following adoption, by a majority of the membership of both houses of the Legislature and signed by the Governor, provided that at least 14 days prior to passage in each house, copies of the bill in final form shall be made available by the clerk of each house to the public and news media.